



PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing
(day/month/year)

21 OCT 2005

Applicant's or agent's file reference

5051.661.WO

IMPORTANT NOTIFICATION

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/03566

15 January 2004 (15.01.2004)

16 January 2003 (16.01.2003)

Applicant

NORTH CAROLINA STATE UNIVERSITY

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application is required, the applicant must contain a translation of any annexes to the international preliminary report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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Form PCT/IPEA/416 (January 2004)

DOCKET

By sa

Date 10/24

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|---|-----------------------|-------------------------------------|-----------|---------------------|--------------------------|------------|----------|--------------------------|-------------|--|--------------------------|------------|----------------------------|-------------------------------------|-----------|---|--------------------------|------------|-------------------------|--------------------------|-------------|--|--------------------------|--------------|---|
| Applicant's or agent's file reference 5051.661.WO | FOR FURTHER ACTION | | See Form PCT/IPEA/416 | | | | | | | | | | | | | | | | | | | | | | | | |
| International application No. PCT/US04/03566 | International filing date (day/month/year) 15 January 2003 (15.01.2004) | Priority date (day/month/year) 16 January 2003 (16.01.2003) | | | | | | | | | | | | | | | | | | | | | | | | | |
| International Patent Classification (IPC) or national classification and IPC IPC(7): C07K 16/42; G01N 33/53; C12N 1/00 and US Cl.: 530/388.1; 435/7.1, 810 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Applicant NORTH CAROLINA STATE UNIVERSITY | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p style="margin-left: 20px;">a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p style="margin-left: 20px;">b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>4. This report contains indications relating to the following items:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 10%;"><input checked="" type="checkbox"/></td> <td style="width: 20%;">Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table> | | | | <input checked="" type="checkbox"/> | Box No. I | Basis of the report | <input type="checkbox"/> | Box No. II | Priority | <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> | Box No. IV | Lack of unity of invention | <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | <input type="checkbox"/> | Box No. VI | Certain documents cited | <input type="checkbox"/> | Box No. VII | Certain defects in the international application | <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. II | Priority | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VI | Certain documents cited | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application | | | | | | | | | | | | | | | | | | | | | | | | | |
| Date of submission of the demand 12 August 2004 (12.08.2004) | | Date of completion of this report 29 September 2005 (29.09.2005) | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230 | | Authorized officer Phoung Huynh Telephone No. (571) 272-1600 | | | | | | | | | | | | | | | | | | | | | | | | | |

Form PCT/IPEA/409 (cover sheet)(January 2004)

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☒ the international application as originally filed/furnished
- ☒ the description:
pages 1-10 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the claims:
pages 11-13 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the drawings:
pages NONE as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/03566**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

| | | |
|-------------------------------|-------------------------------|-----|
| Novelty (N) | Claims <u>1-10, and 17-26</u> | YES |
| | Claims <u>11, and 13-16</u> | NO |
| Inventive Step (IS) | Claims <u>1-10, and 17-26</u> | YES |
| | Claims <u>11-16</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-26</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and Explanations (Rule 70.7)

Claims 1-10 and 17-26 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed antibody that specifically binds to mammalian IgE at an epitope wherein said epitope is between amino acids 145-166 of mammalian IgE and a kit comprising said antibody.

Claims 11 and 13-16 lack novelty under PCT Article 33(2) as being anticipated by Chretien et al (J Immunology, November 1988, Vol. 141, pages 3218-3134).

Chretien et al teach an antibody such as mouse monoclonal antibody mAb 27 that specifically binds to a mammalian IgE such as human IgE at an epitope having amino acids 367-376 which is between amino acids 356-374 of mammalian IgE (see page 3131, col. 2, third paragraph, abstract, page 3132, Fig 4, in particular). The reference antibody is coupled to a detectable group such as fluorescence (see page 3128, col. 2, first paragraph, in particular) or a specific binding pair such as mouse anti-IgG conjugated to alkaline phosphatase and enzyme substrate p-nitrophenylphosphate in diethanolamine buffer (see page 3129, col. 1, Sandwich ELISA, in particular). Thus the reference teachings anticipate the claimed invention.

Claims 11-16 lack an inventive step under PCT Article 33(3) as being obvious over Chretien et al (J Immunology, November 1988, Vol. 141, pages 3218-3134) in view of Griot-Wenk et al (Veterinary Immunology and Immunopathology, 1998, Vol 64, pages 15-32).

The teachings of Chretien et al have been discussed supra.

The claimed invention in claim 12 differs from the teachings of the reference only in that the antibody is a dog IgE instead of human IgE.

Griot-Wenk et al teach dog specific IgE antibodies for detection of antigen-specific IgE in dog serum (see abstract, page 17-19, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the antibody that binds to human IgE as taught by the Chretien et al for the antibody that binds specifically to dog IgE for detecting antigen-specific IgE in dog serum as taught by Griot-Wenk et al. From the combined teachings of the references, it would have had a reasonable expectation of success in producing the claimed invention.

One having ordinary skill in the art would have been motivated to substitute the antibody that binds specifically to human IgE for dog IgE because dog IgE-specific antibody could better detect antigen-specific IgE in dog serum as taught by Griot-Wenk et al (see page 16, first paragraph, in particular).

Claims 1-26 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.